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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,419	04/20/2004	Alfred Berchielli	PC25684A	5347

28880 7590 09/20/2007
WARNER-LAMBERT COMPANY
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EXAMINER	
AHMED, HASAN SYED	
ART UNIT	**PAPER NUMBER**
1615	
MAIL DATE	**DELIVERY MODE**
09/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,419	BERCHIELLI, ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6-12,14,15 and 17-30* is/are pending in the application.

4a) Of the above claim(s) *18-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6-12,14,15 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicants' amendment, which was filed on 29 June 2007.
- The claim objection and 35 USC 102(b) rejection are withdrawn in view of the amendment.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite due to improper form of the Markush claim language. Markush claims are, for example, in the following form: "a compound selected from the group consisting of A, B and C." Since the applicants do not use proper Markush form, it is not known whether applicants intend to use multiple disintegrating agents or a single disintegrating agent.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, 6-12, 14, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson, et al. (WO 99/36060) in view of Kerc, et al. (WO 02/072073).

Wilson, et al. disclose an oral dosage form (*see* page 1, lines 10-19). The dosage form is comprised of:

- the atorvastatin prepared without a granulation step of instant claim 1 (*see* page 5, line 28; examples 1-39);
- the less than about 5% alkalizing agent additive of instant claim 1 (*see* page 10, lines 18-22; examples 1-39);
- the excipient of instant claim 3 (*see* page 7, lines 7-24);
- the less than about 5% alkaline earth metal salt additive of instant claim 6 (*see* examples 1-39);
- the less than about 5% polymeric amide or polymeric amine additive of instant claim 7 (*see* examples 1-39); and
- the at least one active drug in addition to the atorvastatin of instant claim 17 (see page 3, line 23).

The use of a capsule filler or tablet press recited in instant claim 2 is not essential to a determination of patentability of the composition disclosed in the claim. As explained by the court in *In re Thorpe et. al.* (CAFC 1985) 779 F2d 695, "A claim to a composition defined by reference to the process by which it is produced, is not limited to compositions produced by the process recited in the claim."

The Wilson, et al. reference is silent with respect to potency, as recited in instant claim 1. Applicants' composition contains the same components in the same configuration as the prior art. Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

Wilson, et al. explain that their dosage form is beneficial because it results in an enhanced rate and degree of absorption of a pharmaceutically active agent, while minimizing gastric irritation (*see* page 1, lines 10-14).

Wilson, et al. do not explicitly disclose the somewhat disordered (amorphous) forms of atorvastatin recited in instant claim 4, however these forms were known in the pharmaceutical art at the time the instant application was filed (*see* Kerc, et al., abstract; page 5, lines 12-16; tables 1 and 4; page 10, lines 8-13; and examples 1-6).

While Wilson, et al. do not explicitly teach the segregation numbers of instant claims 12 and 15, the mean particle diameter of instant claim 14, or the diluent concentration of instant claim 1, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable segregation, particle diameter, and diluent concentration by routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in segregation, particle diameter, or concentration will not support the patentability of subject matter encompassed by the

prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant segregation number, particle diameter, or diluent concentration.

Wilson, et al. do not explicitly teach the diluents of instant claim 1 (e.g. microcrystalline cellulose). Rather, they teach use of the diluents hydroxypropylmethylcellulose and hydroxypropylcellulose (*see* page 7, lines 14-16). Because microcrystalline cellulose, hydroxypropylmethylcellulose and hydroxypropylcellulose are all carbohydrate-based dispersing agents, one of ordinary skill in the art would have been motivated to add microcrystalline cellulose, hydroxypropylmethylcellulose or hydroxypropylcellulose to the instant composition. There is a reasonable expectation that the addition of microcrystalline cellulose, hydroxypropylmethylcellulose or hydroxypropylcellulose to the instant composition would provide an effective diluent. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add either microcrystalline cellulose, hydroxypropylmethylcellulose or hydroxypropylcellulose to the instant composition.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a unit dosage form comprising a somewhat disordered form of atorvastatin without a granulation step, as taught by Wilson, et al. in view of

Kerc, et al. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it results in an enhanced rate and degree of absorption of a pharmaceutically active agent, while minimizing gastric irritation, as explained by Wilson, et al.

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

*

1. Claims 1, 2, 4, 6-12, 14, 15, and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/828,398 ('398). Although the conflicting claims are not identical, they are not patentably distinct from each other because '398 claims a

composition comprising atorvastatin (claim 1) in a disordered form (claim 7), with low levels of alkaline earth metal salt additive (claim 2).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*

2. Claims 1, 2, 4, 6-12, 14, 15, and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/828,079 ('079). Although the conflicting claims are not identical, they are not patentably distinct from each other because '079 claims a composition comprising atorvastatin (claim 1) in a disordered form (claim 3), with low levels of alkaline earth metal salt additive (claim 1).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

Response to Arguments

Applicant's arguments filed on 29 June 2007 have been fully considered but they are not persuasive.

Applicants argue that the Wilson reference does "...not teach or suggest excipient or combination of excipients comprising greater than about 50 wt% of a diluent or combination of diluents..." recited in amended instant claim 1. *See* remarks, page 8.

As to the claimed diluents, as explained in the substantive rejection above, Wilson, et al. do not explicitly teach the diluents of instant claim 1 (e.g. microcrystalline

cellulose). Rather, they teach use of the diluents hydroxypropylmethylcellulose and hydroxypropylcellulose (*see* page 7, lines 14-16). Because microcrystalline cellulose, hydroxypropylmethylcellulose and hydroxypropylcellulose are all carbohydrate-based dispersing agents, one of ordinary skill in the art would have been motivated to add microcrystalline cellulose, hydroxypropylmethylcellulose or hydroxypropylcellulose to the instant composition. There is a reasonable expectation that the addition of microcrystalline cellulose, hydroxypropylmethylcellulose or hydroxypropylcellulose to the instant composition would provide an effective diluent. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add either microcrystalline cellulose, hydroxypropylmethylcellulose or hydroxypropylcellulose to the instant composition.

As to the concentration of diluents, as explained in the substantive rejection above, while Wilson, et al. do not explicitly teach the diluent concentration of instant claim 1, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable segregation, particle diameter, and diluent concentration by routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955).

Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant diluent concentration.

* * * * *

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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HUMERA N SHEIKH
PRIMARY EXAMINER